DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/14/08 has been entered.

Claim Objections

Claims 1 and 3 are objected to because of the following informalities:

In claims 1 and 3, “the ultrasonic beam direction” and “the blood flow velocity vector” lack antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charbel et al. (US 7191110) in view of Okada et al. (US 6673020) and Kamm et al. (US 6117087) or Cawlfield (US 6088630) or Hayase et al. ("State Estimator of Flow as an Integrated Computational Method with the Feedback of Online Experimental Measurement", Transactions of the ASME, J. Fluids Eng., Vol. 119 (1997), pp. 814-822).

Charbel et al. show, a blood flow visualizing diagnostic apparatus characterized by having: an analysis processing unit which obtains a blood vessel shape (measuring blood vessels, column 13, line 10-50; also column 17, lines 65-67) and a blood flow velocity (measuring blood velocity, column 15, line 45-column 16, line 30; also column 18, lines 1-2 where blood flow constitutes blood velocity) in the blood vessel by the received signal; a simulation unit which sets computational lattices on the basis of the blood vessel shape obtained by said analysis processing unit to simulate the blood flow velocity and a pressure distribution (the polygonal mesh iso-surface can be considered a lattice or the cube could also be considered a lattice, it is generated based on the shape of the blood vessel, and is used to simulate the velocity and pressure, column 14, lines 5-column 18, line 6); a feedback unit which computes an error between the blood

flow velocity obtained by said analysis processing unit and the blood flow velocity obtained by said simulation unit to feed back the error to said simulation unit (the actual data is used to update the simulated model based on the specific patient data, the actual data is fed back to the model and used to adjust the model, although the word "error" is not specifically used, the adjusting of the model based on patient data can be taken to mean that any error between the simulated model and the actual patient data is corrected, column 17, 55-column 18, line 5); and a display unit which displays the blood flow velocity and the pressure distribution output from said simulation unit after the feedback (column 16, lines 30-45). Also, the feedback unit performs the feedback to a sufficiently large number of representative points which are distributed over the blood flow domain in said computational lattices (A "sufficient" number of points are a number of points that are adequate to complete the task, which in this case is generating a customized patient model. Because the obtained result is in fact a model customized to the patient, a "sufficient" number of points must have been adjusted to achieve a customized patient model, column 17, line 55-column 18, line 5); and using ultrasound to measure the blood velocity (column 16, lines 20-25). Charbel et al. fail to show using ultrasound to measure the shape of the blood vessels, the blood velocity, and the blood pressure. Also, Charbel et al. fail to show calculating a difference between real and simulated values.

Okada et al. disclose an ultrasonic diagnostic apparatus. Okada et al. teach, an ultrasonic measurement unit which emits an ultrasonic signal toward a blood vessel inside a human body to receive the reflected ultrasonic signal (using ultrasound to

obtain the size of blood vessels, the velocity of the blood, and the blood pressure, column 2, line 60-column 4, line 60).

Kamm et al. disclose a method and apparatus for noninvasive assessment of a subject's cardiovascular system. Kamm et al. teach that computed features (simulated) can be compared to values obtained from experimental measurements (actual) and a measure of the error or difference between them can be obtained. This difference value can be used to modify the simulated values until the error is sufficiently reduced (column 17, lines 48-64 and Figure 8).

Cawlfield discloses an automatic control system for unit operation. Cawlfield teaches that real values can be compared to simulated values and the difference can be used to update the simulation (column 7, lines 40-46).

Hayase et al. '97 disclose an estimator of flow with feedback of experimental measurement. Hayase et al. '97 teach that a difference between the simulated and experimental values is calculated and fed back to modify the simulation (page 816)

It would have been obvious to one of ordinary skill in the art, at the time the invention as made, to have used ultrasound to measure the shape of the blood vessels, the blood velocity, and the blood pressure as taught by Okada et al., in the system of Charbel et al., with the motivation that ultrasound provides for a suitable and non-invasive imaging means to image blood vessels. Charbel et al. does in fact use Doppler in their blood flow measurements as well, and while no specific mention is made of using ultrasound to obtain the vessel shape, one of ordinary skill in the art would know that ultrasound imaging provides a suitable means to image blood vessels. There is a

reasonable expectation of success to combine these references, because both are related to measuring blood vessel shape, blood velocity, and blood pressure in a patient.

While Charbel et al. show that the actual blood flow can be used to customize the model to the actual patient, they do not go into specific details of how this is accomplished. Computing the difference between real and simulated values, and using the difference to update a simulation is old and well known across a wide variety of arts. Kamm et al., Cawlfield, and Hayase et al. '97 are three examples of using such a technique. It would have been obvious to one of ordinary skill in the art, to have compared the difference between real and simulated values and used the difference to update the simulation as taught by Kamm et al. or Cawlfield or Hayase et al. '97, to have customized the model of the patient with actual blood flow values in the combined system of Charbel et al. and Okada et al.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charbel et al. (US 7191110) in view of Okada et al. (US 6673020) Kamm et al. (US 6117087) or Cawlfield (US 6088630) or Hayase et al. ("State Estimator of Flow as an Integrated Computational Method with the Feedback of Online Experimental Measurement", Transactions of the ASME, J. Fluids Eng., Vol. 119 (1997), pp. 814-822) as applied to claim 1 above, and further in view of Hayase et al. ("Numerical Realization of Flow Field by Integrating Computation and Measurement, Proceedings of 5th World Congress on Computational Mechanics, Vienna, Austria, July 7-12 (2002)).

Hayase et al. ’02 disclose a numerical realization of flow field. Hayase et al. ’02 teach a similar equation where the Navier-Stokes equation includes a component f, the body force corresponding to the feedback signal (page 4). There is a similar equation to claim 3 where the body force is calculated by multiplying a negative value of the feedback gain with the pressure components (page 5). One of ordinary skill in the art calculating velocity of blood could have substituted appropriate values for blood flow as opposed to the pressure.

It would have been obvious to one of ordinary skill in the art, to have computed the feedback component as taught by Hayase et al. ‘02, in the combined system of Charbel et al., Okada et al, and Kamm et al. or Cawlfield or Hayase et al. ’97. Charbel et al. show that actual values of blood flow can be used to update a simulation model. In the absence of any criticality or unexpected result, it would be an obvious design choice to have performed the calculations another way, such as by normalizing the beam direction.

Response to Arguments

Applicant's arguments with respect to claims 1 and 3 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is

(571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/Ruth S. Smith/
Primary Examiner, Art Unit 3737